1. April 2015

FINAL

European Union Comments

CODEX COMMITTEE ON PESTICIDE RESIDUES

47th Session

Beijing, China, 13 – 18 April 2015

AGENDA ITEM 5 a)

Report on items of general consideration by the 2014 JMPR

(**Section 2 of the 2014 JMPR Report**)

European Union Competence

European Union Vote

The European Union (EU) would like to provide the following comments on section 2 of the 2014 JMPR Report:

2.1 Guidance Document for WHO Monographers

It is noted that on 3-5 December 2014 EFSA and WHO have organised a workshop to develop a globally harmonised decision tree for a tiered approach on the application of the TTC in the risk assessment of chemicals. The expert group agreed a series of conclusions and recommendations, which are available for public consultation on the EFSA and WHO websites until 29 March 2015. Comments received will be considered and addressed by the expert group, and an event report will be published in late spring 2015.

It seems premature to recommend already now to use TTC, considering that the discussions following the Joint EFSA /WHO workshop are not yet finalised and the details on the implementation still need to be discussed.

It should be also noted that EFSA is currently working on a number of relevant projects that touch upon the use of the TTC approach, e.g. a project on residue definition.

The new JMPR guidance for monographers has been brought to the attention of the EFSA panel on Plant Protection Products and their Residues for consideration in the context of its mandate to prepare a guidance document on the residue definition for risk assessment. EFSA will submit a draft of this guidance document to public consultation this summer.

2.2 Update on the revision of the Principles and Methods for the Risk Assessment of Chemicals in Food (EHC 240)

The EU welcomes the announced update of EHC 240 on a routine basis. A harmonised approach will help to come to a common understanding and comparable results when assessing toxicological data.

Concerning the TTC approach the EU refers to its comments on point 2.1.

Given that a harmonised approach regarding "Principles and Methods for the Risk Assessment of Chemicals in Food" is available, **the EU would like to take the opportunity**

to ask the WHO why two different organisations sponsored by the WHO, namely the JMPR and the IARC, came to different conclusions when evaluating the active substance glyphosate.

Glyphosate was last re-evaluated by the 2004 Joint FAO/WHO Meeting on Pesticide Residues within the periodic review program of the JMPR.

Concerning the carcinogenicity the JMPR stated: "In view of the absence of a carcinogenic potential in animals and the lack of genotoxicity in standard tests, the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans."

Furthermore, the meeting "established a group ADI for glyphosate and AMPA of 0–1.0 mg/kg bw" and "concluded that it was not necessary to establish an ARfD for glyphosate".

Seventeen experts from 11 countries met at the International Agency for Research on Cancer (IARC) in March 2015 to assess the carcinogenicity of, inter alia, glyphosate.

The Working Group classified glyphosate as "probably carcinogenic to humans" (Group 2A, i. e. carcinogen 1B according to GHS Classification). The outcome of the meeting was published online in form of a short article entitled "Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate" in The Lancet on 20 March 2015.
http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)70134-8/abstract

The complete assessments will be published as volume 112 of the IARC Monographs. They were not yet available at the time these comments were written.

2.3 Hazard assessments in the 21st Century: Incorporating data from new mechanistic-based approaches in JMPR evaluations

The submission of data according to new approaches in parallel to the results of traditional toxicity testing should be encouraged in order to gain experience how this data can be integrated in future hazard assessments.
However, for hazard assessments at EU level the data requirements specified in EU legislation need to be respected. The data according to the new approaches would be considered as supporting information which cannot replace the existing data requirements.

2.4 Cumulative assessment group methodology

From 2008 to 2013, the EFSA Panel on Plant Protection Products and their Residues has adopted a number of opinions and guidance documents to support:

- A tiered methodology to carry out cumulative risk assessments;
- The establishment of cumulative assessment groups of pesticides;
- The assessment of cumulative exposure by probabilistic modelling.

The relevant documents have been published on the EFSA website at the following links:

http://www.efsa.europa.eu/en/efsajournal/pub/705.htm

http://www.efsa.europa.eu/en/efsajournal/pub/1167.htm

http://www.efsa.europa.eu/en/efsajournal/pub/2839.htm

http://www.efsa.europa.eu/en/efsajournal/pub/3293.htm

http://www.efsa.europa.eu/en/efsajournal/pub/3472.htm

EFSA has now started a new programme of work to implement cumulative risk assessment of pesticide residues regarding their chronic effects on the thyroid and their acute effects on the nervous system. Respective scientific reports are expected to be published in 2017.

2.5 Characterization of risk of less-than-lifetime high exposures to ~~ks for~~ pesticides residues

The EU is of the opinion that the assessment of exposure scenarios where the time-weighted average exposure during a shorter than the overall lifetime exposure is higher than the full lifetime exposure is relevant. This is the reason why at EU level chronic exposure assessments are performed specifically for children, because for the period of childhood a higher exposure than for the general population would be expected. Currently the ADI is used for assessing possible risks.

2.6 Incomplete toxicological data packages

In view of the extreme workload for JMPR and to ensure that JMPR can perform the state-of-the art assessments, the EU fully supports the recommendation that sponsors are requested to provide a declaration that all available information has been submitted to JMPR. This approach would help to increase efficiency and avoid that JMRP is forced to reassess studies that were not made available by sponsors in the initially submitted data package.

2.7 Maximum residue limits for pesticides for minor/speciality crops (comments on proposals from the 46th CCPR)

The EU has no specific comments on this point.

2.8 Further consideration of the process for establishing group MRLs

The EU noted that JMPR in 2014 followed a 2- step procedure in some cases to decide whether data sets for different crops can be grouped. This was for instance the case for dimethomorph, fenamidone and fluopyram. The first step consisted of checking whether the median residues of the crops potentially to be grouped differ by less than 5-fold. If they differed by more than 5-fold the datasets were considered non-comparable. If the medians were however within the 5-times range, an additional statistical test was performed. The EU agrees with the approach to use a statistical test to decide whether the datasets belong to the same population or not. The EU is however of the opinion that the first step could be omitted and a statistical test directly applied if the number of trials is sufficient to do so. Furthermore, apart from the statistical test, it should also be taken into account whether the MRLs calculated for the individual commodities would be similar (i.e. whether the same or an adjacent MRL class would be derived by the OECD calculator). If this is not the case, the EU considers the setting of a group MRL as not appropriate.

The comparison of the results in Table 1 demonstrates that the results for representative crops belonging to the group of pome fruit are in general very homogeneous. Thus, for this group extrapolation is a suitable approach. Also for citrus fruit and fruiting vegetables, cucurbits the setting of group MRLs is more likely to work. However for stone fruit the residue data for the individual crops have a high variability. Thus, for this crop group in general the setting of group tolerances seems to be inappropriate. Similarly, residues in crops belonging to the

fruiting vegetables, other than cucurbits, differ significantly with higher residues in peppers than in tomatoes or aubergines.
These findings are very much in line with the EU experiences, which are reflected in the current extrapolation rules used in the EU.

The EU is of the opinion that the new Codex Classification takes these differences into account. Regarding the example of stone fruits given above the new classification divides stone fruit into the subgroups cherries, plums and peaches. Therefore, it is proposed to use the new classification at the earliest possible point in time.

2.9 IESTI calculations for kumquat in relation to group MRLs for "Citrus fruits" and "Lemons"
The EU has no specific comments on this point.

2.10 Update of the GEMS/Food diets for estimation of the IEDI The update of the GEMS/Food diets is welcome. EU Member States were allocated to five different cluster diets (G06: Greece; G07: Finland, France, Iceland, Luxemburg, United Kingdom; G08: Austria, Germany, Poland, Spain; G10: Bulgaria, Croatia, Cyprus, Estonia, Italy, Latvia, Malta; G11: Belgium, Netherlands; G15: Czech Republic, Denmark, Hungary, Ireland, Lithuania, Portugal, Romania, Slovakia, Slovenia, Sweden). The EU will perform comparative assessments to gain experience whether the new cluster diets give results that are considered representative for the EU Member States. In view of the fact that data for single commodities are not available in a non-aggregated form, a splitting factor might be a way for getting more realistic IEDI estimations.